4,902,683

use from which to estimate the economic costs to the industry of mandatory HACCP regulations for foods other than seafood. FDA will use this information in tailoring any HACCP regulations that may issue so that costs and benefits of such regulations are appropriately considered.

FDA estimates the burden of this survey as follows:

#21

ESTIMATED ANNUAL REPORTING BURDEN

Burden Element	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 1—Computer Assisted Telephone Interview (CATI)					
Respond to initial recruitment telephone call	1,231	1	1,231	0.2	246.2
Receive and read introductory letter, key term definitions	1,231	1	1,231	0.25	307.75
Obtain data to prepare for the telephone interview	1,231	1	1,231	0.35	430.85
Respond to telephone interview	1,231	1	1,231	0.5	615.50
Totals		1			1,600.3
Part 2—On-Site Cost Interview					
Receive initial recruitment telephone call	17	1	17	0.2	3.4
Receive and read introductory letter and materials	17	1	17	0.25	4.25
Obtain data to prepare for the site visit	17	1	17	0.5	8.5
Respond to questions during site visit	17	1	17	3.0	51.0
Followup questions	17	1	17	0.25	4.25
Total burden hours, on-site interviews					71.4

There are no capital costs or operating and maintenance costs associated with this collection of information.

The total burden hours for Part 1—CATI and Part 2—On-Site Cost Interview are 1,671.7.

The burden hour estimates are based on a pretest conducted with three focus groups.

Dated: February 20, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-4955 Filed 2-27-97; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96E-0269]

Determination of Regulatory Review Period for Purposes of Patent Extension; EXCENEL® Sterile Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EXCENEL® Sterile Suspension and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product EXCENEL® Sterile Suspension (ceftiofur hydrochloride). EXCENEL® Sterile Suspension is indicated for the treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus (Haemophilus) pleuropneumoniae, Pastureruella multocida, Salmonella choleraesuis*, and *Streptococcus suis* Type 2. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EXCENEL® Sterile Suspension (U.S. Patent No. 4,902,683) from Pharmacia & Upjohn Co. and requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated November 21, 1996, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of EXCENEL® Sterile Suspension represented the first

commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for EXCENEL® Sterile Suspension is 900 days. Of this time, 881 days occurred during the testing phase of the regulatory review period, while 19 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective*: November 10, 1993. FDA has verified the applicant's claim that November 10, 1993, was the date that the investigational new animal drug application became effective.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: April 8, 1996. The applicant claims April 3, 1996, as the date the new animal drug application (NADA) for EXCENEL® Sterile Suspension (NADA 140–890) was initially submitted. However, a review of FDA records reveals that FDA's official acknowledgment that the NADA was sufficiently complete to begin review was a telephone call requesting that certain additional information be added to the NADA on April 8, 1996, which is considered to be the initially submitted date for the NADA.

3. *The date the application was approved*: April 26, 1996. FDA has verified the applicant's claim that NADA 140–890 was approved on April 26, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,151 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 29, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 27, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 20, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–4954 Filed 2–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94D–0259]

"Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a points to consider (PTC) document entitled "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997)." This PTC document is intended to assist sponsors and investigators engaged in monoclonal antibody product development and it includes information to submit when filing investigational new drug applications and product license applications. The document revises a 1994 document entitled "Draft Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use."

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the document entitled "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997)" to the Manufacturers Assistance and Communication Staff (HFM–42), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail or fax by calling the CBER Fax Information System at 1–888–CBER–FAX or 301–827–3844.

Persons with access to the Internet may obtain the document using the World Wide Web (WWW) or bounce-back e-mail. For WWW access, connect to CBER at "http://www.fda.gov/cber/cberftp.html." For bounce back e-mail send a message to "ptc_mab@al.cber.fda.gov."

Submit written comments on the PTC document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the PTC document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a PTC document entitled "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997)." This PTC document supersedes the document entitled "Draft Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use" announced in the Federal Register of August 3, 1994 (59 FR 39571), and is designed to assist sponsors and investigators engaged in monoclonal antibody product development.

The PTC revision was undertaken for reasons that include but are not limited to: (1) Facilitating initial development of monoclonal antibodies for serious and immediately life-threatening indications; (2) updating and streamlining information from the 1994 PTC document; and (3) assuring consistency with current CBER policy and International Conference on Harmonisation documents dealing with this category of products. In the revision of this document, CBER reviewed and considered all comments submitted to the docket.

The PTC document details an approach for sponsors and investigators to follow in product manufacturing and testing, preclinical and clinical studies, and the information to be provided for